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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,183	01/03/2007	Eiji Sunahara	65792(46342)	1851
21874 7590 12/02/2010 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205				
EXAMINER				
HOLLERAN, ANNE L				
ART UNIT		PAPER NUMBER		
1643				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/584,183

Applicant(s)

SUNAHARA ET AL.

Examiner

ANNE L. HOLLERAN

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-8 and 15-24 is/are pending in the application.
- 4a) Of the above claim(s) 15-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed 1/5/2010 is acknowledged.

Claims 1, 3-8 and 15-24 are pending.

Claims 15-24, drawn to non-elected inventions, are withdrawn from consideration.




Claims 1 and 3-8 are examined on the merits.

Objections

The objection to the sequence listing is withdrawn in view of the amendment to the sequence listing.

As evidenced by the following sequence alignment between the newly submitted SEQ ID NO: 1 and reference sequence NP_064595.2, SEQ ID NO: 1 is now corrected. This corrected sequence is the same as the sequence that was present in the databases (Genbank) as of Dec. 12, 2003.

This application has a filing date of 12/22/2004 and foreign priority to a Japanese patent application filed 12/24/2003. Therefore, the correction of the typographical error of SEQ ID NO: 1 does not introduce new matter into the specification as originally filed.

>  ref|NP_064595.2|  semaphorin-4B precursor [Homo sapiens]
ref|NP_945119.1|  semaphorin-4B precursor [Homo sapiens]
dbj|BAG11357.1| semaphorin-4B precursor [synthetic construct]
Length=837

GENE ID: 10509 SEMA4B | sema domain, immunoglobulin domain (Ig), transmembrane domain (TM) and short cytoplasmic domain, (semaphorin) 4B [Homo sapiens] (Over 10 PubMed links)

Score = 1717 bits (4448), Expect = 0.0, Method: Compositional matrix adjust.
Identities = 837/837 (100%), Positives = 837/837 (100%), Gaps = 0/837 (0%)

Query 1 MLRTAMGLRSWLAAAPWGALPPRPPLLLLLLLLLLQPPPTWALSPRISLPLGSEERPFL 60
MLRTAMGLRSWLAAAPWGALPPRPPLLLLLLLLLLQPPPTWALSPRISLPLGSEERPFL

Sbjct	1	MLRTAMGLRSWLAAPWGALPPRPPLLLLLLLLLLLQPPPTWALSPRISLPLGSEERPFL	60
Query	61	RFEAEHISNYTALLLSRDGRTLYVGAREALFALSSNNLSFLPGGEYQELLWGADAEEKQOC RFEAEHISNYTALLLSRDGRTLYVGAREALFALSSNNLSFLPGGEYQELLWGADAEEKQOC	120
Sbjct	61	RFEAEHISNYTALLLSRDGRTLYVGAREALFALSSNNLSFLPGGEYQELLWGADAEEKQOC	120
Query	121	SFKGKDPQRDCQNYIKILLPLSGSHLFTCGTAAFSMCTYINMENFTLARDEKGNVLLED SFKGKDPQRDCQNYIKILLPLSGSHLFTCGTAAFSMCTYINMENFTLARDEKGNVLLED	180
Sbjct	121	SFKGKDPQRDCQNYIKILLPLSGSHLFTCGTAAFSMCTYINMENFTLARDEKGNVLLED	180
Query	181	GKGRCPFDPNFKSTALVVDGELYTGTVSSFOGNDPAISRQSRLRPTKTESSLNLWQDPAF GKGRCPFDPNFKSTALVVDGELYTGTVSSFOGNDPAISRQSRLRPTKTESSLNLWQDPAF	240
Sbjct	181	GKGRCPFDPNFKSTALVVDGELYTGTVSSFOGNDPAISRQSRLRPTKTESSLNLWQDPAF	240
Query	241	VASAYIPESLGSQGGDDDKIYFFSETGQEFEFFENTIVSRIARICKGDEGGERVLQQRW VASAYIPESLGSQGGDDDKIYFFSETGQEFEFFENTIVSRIARICKGDEGGERVLQQRW	300
Sbjct	241	VASAYIPESLGSQGGDDDKIYFFSETGQEFEFFENTIVSRIARICKGDEGGERVLQQRW	300
Query	301	TSFLKAQLLCSRDDGFFPNVLQDVFTLSPSPQDWRDTLFYGVFTSQWHRGTTEGSACV TSFLKAQLLCSRDDGFFPNVLQDVFTLSPSPQDWRDTLFYGVFTSQWHRGTTEGSACV	360
Sbjct	301	TSFLKAQLLCSRDDGFFPNVLQDVFTLSPSPQDWRDTLFYGVFTSQWHRGTTEGSACV	360
Query	361	FTMKDVQRVFSGLYKEVNRETQQWYTVTHPVPTPRPGACITNSARERKINSSQLPDRVL FTMKDVQRVFSGLYKEVNRETQQWYTVTHPVPTPRPGACITNSARERKINSSQLPDRVL	420
Sbjct	361	FTMKDVQRVFSGLYKEVNRETQQWYTVTHPVPTPRPGACITNSARERKINSSQLPDRVL	420
Query	421	NFLKDHFLMDGQVRSRMLLLQPQARYQVAVHRVPGHLHHTYDVFLGTGDRGLHKAVSVG NFLKDHFLMDGQVRSRMLLLQPQARYQVAVHRVPGHLHHTYDVFLGTGDRGLHKAVSVG	480
Sbjct	421	NFLKDHFLMDGQVRSRMLLLQPQARYQVAVHRVPGHLHHTYDVFLGTGDRGLHKAVSVG	480
Query	481	PRVHIEELQIFSSGQPVQNLLLDTHRGLLYAASHSGVVQVPMANCSLYRSCGDCLLARD PRVHIEELQIFSSGQPVQNLLLDTHRGLLYAASHSGVVQVPMANCSLYRSCGDCLLARD	540
Sbjct	481	PRVHIEELQIFSSGQPVQNLLLDTHRGLLYAASHSGVVQVPMANCSLYRSCGDCLLARD	540
Query	541	PYCAWSSGSSCKHVSLYQPQLATRPWIQDIEGASAKDLCSASSVSPSFVPTGEKPCQVQ PYCAWSSGSSCKHVSLYQPQLATRPWIQDIEGASAKDLCSASSVSPSFVPTGEKPCQVQ	600
Sbjct	541	PYCAWSSGSSCKHVSLYQPQLATRPWIQDIEGASAKDLCSASSVSPSFVPTGEKPCQVQ	600
Query	601	FQPNVTNTLACPLLSNLATRLWLRNGAPVNASASCHVLPTGDLLLVGTQQLGEFQCSLE FQPNVTNTLACPLLSNLATRLWLRNGAPVNASASCHVLPTGDLLLVGTQQLGEFQCSLE	660
Sbjct	601	FQPNVTNTLACPLLSNLATRLWLRNGAPVNASASCHVLPTGDLLLVGTQQLGEFQCSLE	660
Query	661	EGFQQLVASYCPEVVEDGVADQTDDEGGSVPVIIISTSRVAPAGGKASWGADRSYWKEFLV EGFQQLVASYCPEVVEDGVADQTDDEGGSVPVIIISTSRVAPAGGKASWGADRSYWKEFLV	720
Sbjct	661	EGFQQLVASYCPEVVEDGVADQTDDEGGSVPVIIISTSRVAPAGGKASWGADRSYWKEFLV	720
Query	721	MCTLFVLAVLLPVFLFLYRHRNSMKVFLKQGECA SVHPKTCPPVLPETRPLNGLGPPST MCTLFVLAVLLPVFLFLYRHRNSMKVFLKQGECA SVHPKTCPPVLPETRPLNGLGPPST	780
Sbjct	721	MCTLFVLAVLLPVFLFLYRHRNSMKVFLKQGECA SVHPKTCPPVLPETRPLNGLGPPST	780
Query	781	PLDHRGYQSLSDSPPGSRVFTSEKRPISIQDSFVEVSPVCPRPVRVLGSEIRDSV PLDHRGYQSLSDSPPGSRVFTSEKRPISIQDSFVEVSPVCPRPVRVLGSEIRDSV	837
Sbjct	781	PLDHRGYQSLSDSPPGSRVFTSEKRPISIQDSFVEVSPVCPRPVRVLGSEIRDSV	837

Claim Rejections Withdrawn:

Claim Rejections - 35 USC § 101

The rejection of claims 1-3 and 5-14 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the amendment to the claims.

Claim Rejections - 35 USC § 112-second paragraph

The rejection of claims 1-14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in view of the amendment to the claims.

Claim Rejections - 35 USC § 112-first paragraph

The rejection claims 1-14 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement in view of the amendment to the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-8 under 35 U.S.C. 102(b) as being anticipated by Herold (Herold, C., et al., Int. Immunology 7: 1-8, 1994) is withdrawn in view of the amendment to the claims.

The rejection of claims 1-14 under 35 U.S.C. 102(b) as being anticipated by Herold (Herold, C., et al., *Int. Immunology* 7: 1-8, 1994) as evidenced by Giordano (Giordano, S., et al. *Nature Cell Biology*, 4: 720-724, 2002; cited in the IDS) is withdrawn in view of the amendment to the claims.

Claim Rejections Maintained and New Grounds of Rejection:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-8 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15, 25, 26, 29, 30, 43-48, 52-54, and 58-63 of copending Application No. 10/540,394. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 15, 25, 26, 29, 30, 43-48, 52-54, and 58-63 of copending application no. 10/540,394 are drawn to pharmaceutical

compositions comprising an antibody that bind to SEQ ID NO: 1 and is characterized as an apoptosis promoter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants' remarks with respect to holding this provisional rejection in abeyance are noted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

Claims 1 and 3-7 are drawn to antibodies that inhibit the binding of a protein comprising the amino acid sequence represented by SEQ ID NO: 1 to a protein comprising the amino acid sequence represented by SEQ ID NO: 26. The amino acid sequence of SEQ ID NO: 1 is the amino acid sequence of semaphorin-4B. The amino acid sequence of SEQ ID NO: 26 is the amino acid sequence of plexin B1. The claims do not specify the nature of the antigen to which the antibody binds. Claim 8 is drawn to an antibody that inhibits the activity of a protein

comprising the amino acid sequence represented by SEQ ID NO: 1. Claim 8 does not specify the nature of the antigen to which the antibody binds.

The specification provides 4 affinity purified polyclonal antibody preparations AS-2531, AS-2532, AS-2591 and AS-2592, which were made by immunizing rabbits with peptides of 12-15 amino acids in length from SEQ ID NO: 1 (SEQ ID NOS: 22-25) coupled to keyhole limpet hemocyanin (pages 91-92). Antibodies AS-2532, AS-2591 and AS-2592 recognized SEMA4B (SEQ ID NO: 1) at a position near 100 kD molecular weight (pages 92-93). Each of antibodies AS-2531, AS-2532, AS-2591 and AS-2592 were able to immunoprecipitate SEMA4B protein (recognized non-denatured SEMA4B; see page 94). Antibodies AS-2531 and AS-2532 were able to induce apoptosis in non-small lung cancer cell line NCI-H2228 (page 100-101). Antibodies 1, 2 and 4 were able to inhibit the binding of SEMA4B to plexin B1 by 63%, 74% and 60%, respectively (see page 108-109), and were able to inhibit the in vitro growth of NCI-H358 cell line (see page 109-111). The exemplified antibodies bind to specific regions of SEQ ID NO: 1, whereas the scope of the claims is much broader, encompassing antibodies that bind to any antigen as long as the antibody has the ability to inhibit the binding of SEQ ID NO: 1 to SEQ ID NO: 26, or inhibit the activity of SEQ ID NO: 1.

For a claim drawn to a genus, the written description requirement may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A

“representative number of species” means that the species, which are adequately described, are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus (see Official Gazette 1241 OG 174, January 30, 2001).

The exemplified antibodies are not representative of the scope of the claims because the exemplified antibodies bind to specific regions of SEQ ID NO: 1, whereas the scope of the claims is much broader encompassing antibodies claimed by functional attributes. With respect to the general functional limitation found in claim 8, inhibiting the function of SEQ ID NO: 1, the specification has not described all of the functions of SEQ ID NO: 1. With respect to binding of SEQ ID NO: 1 to SEQ ID NO: 26, the specification has not described the regions of SEQ ID NO: 1 or of SEQ ID NO: 26, nor any other possible additional proteins that are responsible for the binding between these two proteins.

Because the specification fails to provide a representative number of species with respect to the broad scope of the claims and because the specification has not correlated structure with function, the specification fails to provide an adequate description of the full scope of the claimed antibodies.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 3-8 are rejected under 35 U.S.C. 102(a) as being anticipated by Sunahara (WO 2004/058817; published July 15, 2004; cited in the IDS).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

The inventive entity for the instant application is Sunahara and Ishii, whereas the inventive entity for “Sunahara” (WO 2004/058817) is Sunahara, Ishii, Yamamoto, and Sato. Therefore, the inventive entity of “Sunahara” is different from that of the instant application.

Sunahara discloses antibodies AS-2531, AS-2532, AS-2591 and AS-2592, which are the same as the antibodies disclosed in the instant application as those having the properties listed in the instant claims (see page 83, lines 8-9 of Sunahara). Therefore, Sunahara discloses the same antibodies as claimed.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu, can be reached on (571) 272-0839. Any inquiry of a general nature or relating to the status

of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

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